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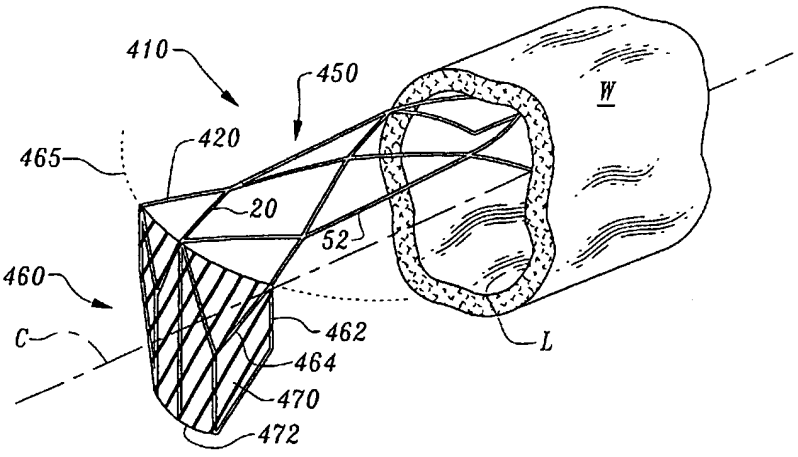
(54) Title: RADIALLY EXPANDABLE STENT FEATURING COVERING TIP PRIMARILY FOR BIFURCATED ARTERY ANEURYSMS



(57) Abstract: A radially expandable stent (10) is provided with a generally cylindrical contour between a distal end (12) and a proximal end (14). The distal end (12) includes a covering tip (60) attached to other portions of the stent (10) through an extension (50) spanning a gap (50) near the distal end (12) of the stent (10). The covering tip (60) extends partially away from the cylindrical contour of the stent (10) and toward a center line of the stent (10). The covering tip (60) includes a surface layer (70) which precludes blood and other fluid flow through the covering tip (60). The stent (10) is formed with a material having a bias towards a final expanded configuration with the covering tip (60) extending away from the cylindrical contour towards the centerline C of the stent (10). The stent (10) is sufficiently flexible so that the covering tip (60) can be initially oriented axially when in an original collapsed configuration and then angled towards the centerline C when the stent (10) is radially expanded. The covering tip (60) can be oriented blocking a neck N of an aneurysm X which faces a blood vessel or other body lumen L. The stent (10) radially expands to engage walls W of the body lumen L with the covering tip (60) blocking the neck N of the aneurysm X so that expansion or rupture of the aneurysm X is precluded.

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RADIALLY EXPANDABLE STENT FEATURING COVERING TIP PRIMARILY FOR BIFURCATED ARTERY ANEURYSMS

Technical Field

The following invention relates to surgically implantable structures for treatment of aneurysms. More particularly, this invention relates to surgically implantable structures which include surfaces that block a neck of the aneurysm to preclude fluid flow into the aneurysm and prevent further expansion and/or rupture of the aneurysm.

Background Art

Aneurysms are bulges in a body lumen, such as a blood vessel. Aneurysms are relatively common especially in the larger arteries throughout the body. Aneurysms are related to the absence of a muscular layer that makes up part of the blood vessels, that over time stretches and thins to create the aneurysm. Aneurysms can break resulting in internal bleeding and related complications.

Brain aneurysms are of particular concern because rupture of a brain aneurysm can cause a stroke or death. Studies have shown that between 1% and 5% of the general population have brain aneurysms and that four hundred thousand people in the United States have brain aneurysms of a significant size. While smaller aneurysms (under 6 millimeters) are very unlikely to bleed, approximately thirty thousand people in the United States suffer from an aneurysm rupture every year. It has been estimated that 60% of such ruptures result in death and 20% of such ruptures result in disability. Accordingly, a need exists for effective treatment to reduce the incidence of brain aneurysm rupture.

Known prior art techniques for treatment of aneurysms include direct surgery and endovascular surgery. With direct surgery, the aneurysm is accessed by making incisions in the skin and opening the skull to locate the aneurysm. The neck of the aneurysm is identified where the ballooned aneurysm connects to the blood vessel. Typically the aneurysm is repaired by placing a clip across the neck. Blood flow is then restricted from passing into the aneurysm and continuing to cause ballooning of the aneurysm, which leads to rupture.

With endovascular surgery a catheter enters the body, typically through a leg artery, and is passed up to the location of the aneurysm under x-ray guidance. The aneurysm is then filled to decrease or eliminate blood flow into the aneurysm, which leads to aneurysm rupture. It is known

in the prior art to fill the aneurysm with tiny coils of material or to fill tiny latex or silicone balloons within the aneurysm.

United States Patent No. 5,350,397 is directed to an axially detachable embolic coil assembly which can be discharged from a catheter and used to fill an aneurysm. Other known prior art coil assemblies are disclosed in the following United States patents: 5,217,484; 5,234,437; 5,250,071; 5,261,916; 5,263,964; 5,562,698; 5,578,074; and 5,601,600.

While direct surgery and use of aneurysm clips is generally effective, it requires invasive surgery and the attendant discomfort and risk of complications. While endovascular surgery is less invasive and can more effectively access some blood vessels and other body lumens, the known technique of filling the aneurysm with coils or balloons is not entirely satisfactory. Specifically, when the coils are utilized a risk of displacement exists and the coil can come out of the aneurysm and do damage within the blood vessel, including causing a stroke. The coils are not affixed in any manner within the aneurysm, enhancing this risk. When coils and balloons are utilized to fill the aneurysm, some risk exists that the aneurysm will rupture during the endovascular procedure. For instance, when the coil is released the coil can put sufficient stress on the aneurysm wall to cause the aneurysm to rupture. Similarly, while the balloon is being filled within the aneurysm, it can be overfilled and cause the aneurysm to rupture. Accordingly, a need exists for a new method and apparatus for treatment of aneurysms.

Disclosure of Invention

The radially expandable stent of this invention includes a tip which extends in toward a center line of the stent for covering a neck of an aneurysm adjacent the tip. The radially expandable stent can have any of a variety of configurations, such as those known in the prior art, which allow the stent to have an original collapsed form of lesser diameter and a final radially expanded form of larger diameter. A covering tip is provided adjacent a distal end of the stent. This covering tip includes a surface layer. The tip is oriented to extend in toward the center line of the stent and away from a cylindrical contour formed by other portions of the stent. A gap is provided between the covering tip and adjacent portions of the stent so that blood and other body fluids can flow through the gap without obstruction by portions of the stent. The stent includes an extension which spans the gap and connects the covering tip to other portions of the stent.

When an aneurysm is located between branches of a body lumen such as a blood vessel, with a neck of the aneurysm approximately facing a centerline of one of the branches, the stent can be installed within the branch which the neck of the aneurysm faces. The covering tip of the stent is oriented adjacent the neck of the aneurysm to at least partially block the neck of the aneurysm. The gap in the stent allows blood flow to pass between the different branches adjacent the aneurysm with blood flow into the aneurysm sufficiently diverted so that expansion and/or rupture of the

aneurysm is prevented. The stent is radially expanded so that it engages walls of the lumen and securely maintains its position.

When the stent is in its original collapsed form for intraluminal positioning at the aneurysm site, the covering tip extends axially with other portions of the stent and is collapsed along with other portions of the stent. The stent includes segments which connect to ribs within the covering tip which are preferably all formed from a shape memory material such as nickel titanium. Such material has a bias toward a final position but can be manipulated into an original collapsed cylindrical form with the ribs of the covering tip extending axially without permanent deformation of the stent, provided that the stent material is brought below a transition temperature for the nickel titanium or other shape memory material. A delivery tube can then surround the stent in its original collapsed form to maintain this position. When the delivery tube is removed from the stent, and the transition temperature is exceeded, the stent automatically returns to its biased final expanded position with the covering tip extending in toward the central axis of the stent and with other portions of the stent expanding radially and engaging walls of the body lumen.

Brief Description of Drawings

Figure 1 is a top plan view of the stent of this invention as it is being deployed from a delivery tube and with a covering tip shown extending axially before it bends in toward the central axis of the stent.

Figure 2 is a front elevation view of that which is shown in Figure 1 and with the bending of the covering tip toward the central axis shown in phantom.

Figure 3 is a sectional view of a blood vessel with an aneurysm located between branches in the blood vessel and with a shortened variation of the stent of Figure 1 implanted within the blood vessel with the covering tip blocking the neck of the aneurysm and leaving blood flow unobstructed.

Figure 4 is a top plan view of a portion of that which is shown in Figure 1 and with the surface layer removed from the covering tip to show details of the ribs of the covering tip.

Figure 5 is a top plan view of a portion of that which is shown in Figure 1 showing details of the covering tip.

Figure 6 is a cylindrical projection of a stent according to a first alternative embodiment of this invention, featuring a unique extension and unique covering tip.

Figure 7 is a cylindrical projection of a stent according to a second alternative embodiment of this invention with a second unique extension and with a covering tip similar to the covering tip of Figure 6.

Figure 8 is a top plan view of the alternative covering tip of Figure 6 with the surface layer removed to reveal rib details for this alternative covering tip.

Figure 9 is a top plan view of a stent according to a third alternative embodiment with the surface layer of the covering tip removed to reveal details of the unique rib configuration of the covering tip of this third alternative embodiment.

Figure 10 is a detailed sectional view taken along line 10-10 of Figure 5 and revealing a preferred surface layer attachment configuration for the covering tip of the stent of this invention.

Figure 11 is a sectional view of a body lumen having an aneurysm between branches in the body lumen and with a stent according to a fourth alternative embodiment deployed within the lumen and with a curving covering tip adjacent a neck of the aneurysm.

Figure 12 is a top plan view of the fourth alternative embodiment stent of Figure 11 immediately prior to rotation of the covering tip about a curving bend line.

Figure 13 is a perspective view of a portion of that which is shown in Figure 11 with portions of the body lumen cut away to reveal details of the deployed fourth alternative embodiment stent including a curving covering tip.

Best Modes for Carrying Out the Invention

Referring to the drawings, wherein like reference numerals represent like parts throughout the various drawing figures, reference numeral 10 is directed to a stent that is radially expandable and features a covering tip 60 at a distal end 12 of the stent 10 (Figures 1 and 2). The covering tip 60 can be located over a neck N of an aneurysm X (Figure 3) to divert blood flow D from passing into the aneurysm X and stop aneurysm X expansion or rupture, while remaining portions of the stent 10 hold the covering tip 60 in place adjacent the neck N of the aneurysm X.

In essence, and with particular reference to Figures 1 and 2, the basic details of the stent 10 are described. The stent 10 has a generally cylindrical contour made up of a plurality of segments 20 which are joined together at junctions 30. The stent 10 can transition between an original collapsed configuration and a final expanded configuration having a greater diameter than the original collapsed configuration. The stent 10 can thus be delivered intravascularly while within a delivery tube 2 (Figure 1) and then be removed from the delivery tube 2 to expand radially (along arrow R) to engage walls of a body lumen L, such as a blood vessel (Figure 3).

A gap 40 is provided adjacent the distal end 12 of the stent 10. The gap 40 is a region on the stent 10 where segments 20 are left out so that blood flow D (Figure 3) laterally away from a centerline C (Figures 1 and 2) of the stent 10 can occur without being impeded by any segments 20 of the stent 10 or other portions of the stent 10. An extension 50 spans the gap 40 and connects the covering tip 60 to the stent 10.

The covering tip 60 includes various ribs 62, 64 which support a surface layer 70 so that the covering tip 60 can effectively block blood flow from passing through the covering tip 60. The covering tip 60 is initially oriented substantially axially when the stent 10 is in its original collapsed

configuration. When the stent is radially expanded, along arrow R, the covering tip 60 rotates, along arrow B (Figure 2), to a position which extends in toward the centerline C. The covering tip 60 is then in position to block the neck N of the aneurysm X while keeping the gap 40 open adjacent the aneurysm X so that blood flow D can continue without obstruction to side branches of the body lumen L (Figure 3).

More specifically, and with particular reference to Figures 1 and 2, specific details of the stent 10 of the preferred embodiment of this invention are described. The stent 10 exhibits a generally cylindrical form with a plurality of segments 20 extending between junctions 30 to make up the cylindrical form of the stent 10. The cylinder formed by the stent 10 is not walled or enclosed. Rather, the segments 20 and junctions 30 are merely located so that they each lie in a manner which, when they are all considered together, lie along a common substantially cylindrical contour.

Stents have been proposed and manufactured having a variety of different segment and junction configurations. For instance, a single segment can extend helically to form a cylindrical stent. A full discussion of various stent segment patterns is provided in *Handbook of Coronary Stents*, Second Edition. Any of the prior art stents disclosed in that reference or otherwise known in the prior art which exhibit radial expandability could conceivably be adapted for use within the stent 10 of this invention.

For convenience, a stent 10 having a multiple linear segment 20 pattern is provided with junctions 30 between ends of each of the segments 20. The segments 20 are oriented substantially axially (along arrow A of Figure 1) before radial expansion, along arrow R of Figure 1 (see portions of the stent 10 located within the delivery tube 2 of Figure 1). When the stent 10 is radially expanded, along arrow R, the segments 20 transition into an orientation which is less axially aligned.

Preferably, the stent 10 radially expands to the point where the segments 20 diverge from an axial orientation by 19° when the stent 10 is radially expanded. Preferably, each segment 20 extends approximately 0.1000 inches axially when the stent 10 is radially expanded. Each segment 20 preferably is 0.0020 inches thick. The stent 10 preferably has a compressed diameter of 0.012 inches and an expanded diameter of 0.120 inches. When radially expanded, the length and width of the segments 20, along with the expanded angular deviation from axial orientation of 19° provides the stent 10 with an approximately ten times expansion coefficient. Of course the amount of radial expansion, along arrow R of Figure 1, can be increased by increasing the length of the segments 20 or by increasing an amount of angular displacement of the segments 20 away from the axial orientation when radially expanded. To add strength to the covering tip 60, the ribs 62, 64 are preferably 0.0030 inches thick.

The segments 20 and junctions 30 which form the stent 10 can be made from a variety of different bio-compatible materials. Preferably however, the segments 20, junctions 30, ribs 62, 64 and joints 66 of the stent 10 are formed from a shape memory nickel titanium alloy. Such nickel titanium alloys are unique in that they can be treated in a manner which gives the stent a

preferred form to which the stent 10 is biased, when a particular temperature, in this case body temperature, is attached. When the stent 10 is cooled to below a transition temperature, the stent 10 becomes much more malleable and can be easily collapsed. When the stent 10 is heated back to its transition temperature, it elastically seeks the form for which it was originally biased. The details associated with the formation and biasing of such shape memory stents are disclosed in detail in United States Patent No. 6,042,606, incorporated herein by reference. Alternatively, the stent 10 can be formed from plastically deformable metal alloys, such as stainless steel.

Because aneurysms are enlarged and/or experience rupture due to exposure to blood flow into the aneurysm X (Figure 4) the stent 10 of this invention desirably blocks such blood flow from passing into the aneurysm X. Specifically, the stent 10 includes a covering tip 60 which is preferably sized to be at least as large as a neck N of the aneurysm X, defining a portion of the aneurysm X between the healthy wall W of the lumen L and the aneurysm X. The covering tip 60 can have any of a variety of shapes and sizes to match the shape of the neck N of the aneurysm X and to otherwise be conveniently supported by structural portions of the stent 10. Figures 1, 2, 4 and 5 show a preferred form of the stent 10 where the covering tip 60 is configured as a rectangle with side edges 74 parallel to an axial direction A (Figure 1) and a free edge 72 perpendicular to the side edges 74.

The surface layer 70 of the covering tip 60 can be formed from any of a variety of different flexible materials. To allow the covering tip 60 to be collapsed along with the segments 20, junctions 30, ribs 62, 64 and joints 66 of the stent 10, it is necessary that the covering tip 60 exhibit flexibility. Most preferably, the surface layer 70 of the covering tip 60 is formed from a parylene film between 0.0001 and 0.002 inches thick, with 0.0005 inches considered ideal.

Parylene is the generic name for members of a family of polymeric di-para-zylylenes. Parylene refers to such thermoplastic polymers that can be formed on surfaces exposed to a rarefied gas in a vacuum. To form the surface layer 70 covering tip 60, the parylene can either be deposited onto a mandrel or other deposition surface laying adjacent where the surface layer 70 is to be formed during the vacuum deposition process. Alternatively, a thin flexible base layer can be located where the surface layer 70 is to be formed and then the parylene can be deposited directly onto this base layer to form the parylene surface layer 70. If desired, the entire stent 10, including the segments 20 and junctions 30 can be coated with the parylene that forms the surface layer 70 also.

As an alternative, the surface layer 70 covering tip 60 can be formed as a silicone film or from high strength copolymers of silicone and a polycarbonate, such as products marketed under the trademark Chronoflex manufactured by Cardiotech International, Inc. of Woburn, Massachusetts. Other appropriate materials, such as polyesters or polytetrafluoroethylene, or any other appropriate flexible surface materials can be utilized to form the surface layer 70 of the covering tip 60.

With particular reference to Figure 10, additional details of the surface layer 70 and its positioning relative to the ribs 62, 64 are described. While the surface layer 70 can be in a variety of different positions relative to the ribs 62, 64 and other structures within the covering tip 60, the

surface layer 70 is preferably configured as shown in Figure 10. Figure 10 provides a detailed sectional view of a portion of the covering tip 60 as shown in Figure 5. Specifically, the covering surface 70 both surrounds the axial ribs 62 and other structural members of the covering tips 60 and provides a smooth surface, preferably located on an inside surface facing the blood flow D. To achieve this detailed configuration for the surface layer 70, two portions of the surface layer 70 can be provided. First, an outside half layer 71 is provided which surrounds three sides of the axial ribs 62 or other structural element of the covering tip 60 and spans space between adjacent ribs 62, 64. This first outside one half layer 71 is preferably 0.00025 inches thick. A second inside half layer 73 is provided inside of the outside first half layer 71 and surrounds a fourth remaining inner surface of the axial ribs 62 or other structural element of the covering tip 60. This second inside half layer 73 is preferably 0.00025 inches thick. The second inside half layer 73 includes an inside surface 75 which is entirely smooth and allows blood flow D against the inside surface 75 to occur without any turbulence inducing disruptions. The two half layers 71, 73 together provide the parylene layer 70 with a thickness of 0.0005 inches. While the surface layer 70 attachment to the covering tip 60 is preferably as shown in Figure 10, other attachment configurations could also be utilized such as with the surface layer 70 medially located between inner and outer surfaces of structural portions of the stent 10 or adjacent the cylindrical outer surface of the stent 10.

The surface layer 70 must be sufficiently flexible so that it does not crack or otherwise break when the stent 10 is in its compressed form within the delivery tube 2. The surface layer 70 must also be sufficiently thin that it does not decrease the ability of the stent 10 to be collapsed into the delivery tube 2. Once the stent 10 is expanded, the surface layer 70 of the covering tip 60 must be sufficiently strong to resist pressure applied to the covering tip 60 due to blood and other fluid flow against the covering tip 60 and other stresses associated with cooling and deploying the stent 10.

The covering tip 60 can be coupled to the distal end 12 of the stent 10 in a variety of different ways. Preferably, the covering tip 60 is not coupled directly to the distal end 12 of the stent 10, but rather is coupled to an extension 50 extending between the covering tip 60 and other portions of the stent 10. Specifically, the stent 10 preferably includes perimeter segments 22 which attach to other segments 20 of the stent 10 through junctions 30 in a direction facing the proximal end 14 of the stent 10, but these perimeter segments 22 define an edge of the gap 40 on the side of the perimeter segments 22 facing the distal end 12 of the stent 10. The gap 40 is formed by omitting segments which would otherwise be necessary to define the complete substantially cylindrical contour of the stent 10. The gap 40 is provided so that blood flow laterally away from the centerline C of the stent 10 can occur into side branches of the body lumen L, such as along arrow D (Figure 3), with minimal obstruction by the segments 20 forming the stent 10.

The extension 50 spans the gap 40 to securely hold the covering tip 60 in position relative to other portions of the stent 10. The extension 50 must balance secure structural support of the

covering tip 60 with minimal obstruction of blood flow D (Figure 3) to maximize the performance of the stent 10. Preferably, the extension 50 is configured with segments 20 coupled to a junction 30 which mirrors a pattern which is provided by other portions of the stent 10 but without repetition circumferentially surrounding the centerline C of the stent 10. Rather, four segments 20 radiate from a single junction 30 with two of the segments 20 extending proximally and coupled to perimeter segments 22 and two segments 20 within the extension 50 and extending distally to connect to additional segments 20 which support the covering tip 60.

To provide additional structural rigidity to the extension 50, axial segments 52 are preferably provided which extend directly from the perimeter segments 22 to the segments 20 extending between the extension 50 and the covering tip 60. Such axial segments 52 enhance a structural strength of the extension 50 so that the covering tip 60 is properly held in position. Because the axial segments 52 extend axially, unlike the segments 20, the axial segments 52 do not extend circumferentially down into the gap 40 and minimize blockage of the gap 40. While this is the preferred form for the extension 50, alternative embodiments could be utilized for the extension 50, such as those which are described in detail below in conjunction with Figures 6 and 7.

With particular reference to Figures 4 and 5, specific details of the covering tip 60 and surface layer 70 are described. The covering tip 60 includes the combination of ribs 62, 64 and joints 66 to provide structural support for the covering tip 60, and a surface layer 70 supported by the ribs 62, 64 and joints 66 which blocks blood or other fluid flow into the aneurysm X when the stent 10 is installed adjacent the aneurysm X (Figure 3). The covering tip 60 preferably includes multiple axial ribs 62 extending distally away from the extension 50 to free ends 63. Angled ribs 64 extend along lines skewed relative to an axial direction and are coupled to the axial ribs 62 at joints 66. Joints 66 also couple the ribs 62, 64 to segments 20 within the extension 50.

A bend line 65 defines a transition between the extension 50 and the covering tip 60. The bend line 65 preferably extends linearly along a line perpendicular to the centerline C and passes through joints 66 of the covering tip 60. Alternatively, the bend line 65 can pass through midpoints of ribs 62, 64 and/or segments 20 within the extension 50.

The bend line 65 defines a location at which the stent 10 is configured so that when the stent 10 is transitioning from its original collapsed configuration to its final expanded configuration the covering tip 60 will bend about the bend line 65 and toward the center line C, along arrow B (Figure 2). This bend line 65 is defined during the manufacture of the stent 10, as discussed in detail below, by providing portions of the segments 20 and/or ribs 62, 64 and joints 66 at the bend line 65 with a bias toward a position which will cause the covering tip 60 to angle down toward the centerline C.

The surface layer 70 includes a free edge 72 coextensive with the free end 63 of the axial ribs 62 and side edges 74 extending axially along the axial ribs 62 which define side edges of the covering tip 60. A connected edge 76 of the surface layer 70 preferably extends along the bend line 65. With this configuration, the surface layer 70 has a generally rectangular form and the

entire covering tip 60 is covered by the surface layer 70.

However, numerous alternatives to the configuration of the covering tip 60 and/or the surface layer 70 could be utilized to still effectively block the neck N of the aneurysm X and otherwise divert blood flow with the stent 10 of this invention. For instance, the axial ribs 62 at edges of the covering tip 60 could be shorter than axial ribs 62 within an interior of the covering tip 60 and the surface layer 70 could follow the free ends 63 of the axial ribs 62 so that the free edge 72 of the surface layer 70 would in fact be curved or beveled adjacent corners of the covering tip 60. Such a configuration might decrease the presence of sharp corners which might damage the body lumen L when the stent 10 is in position. It is also conceivable that the covering tip 60 would be custom configured to match the shape and size of the neck N of the aneurysm X to maximize the ability of the covering tip 60 to block blood flow into the aneurysm X.

With particular reference to Figure 1-3, details of the use and operation of the stent 10 of the preferred embodiment are described. Initially, the stent 10 has its segments 20 and junctions 30 formed according to the pattern desired to provide the performance desired for the stent 10. While this stent 10 forming process can occur in a variety of ways, it typically involves cutting of the segments 20 and junctions 30 from a cylindrical tube of nickel titanium. This tube is then biased by heat treating the tube while the tube is held in a configuration which is to be the biased diameter. If necessary, this heating step occurs while the structure of the stent 10 is forced to be expanded or collapsed somewhat from its original diameter when cut from the tube. After this heat treatment, the stent 10 will be biased toward the diameter which existed when the heat treatment occurred.

The biasing heat treatment is performed on the stent 10 after the portions of the stent 10 forming the covering tip 60 have been bent about the bend line 65 to the desired final expanded orientation. The heat treatment then causes this inwardly extending covering tip 60 orientation to be the position to which the covering tip 60 is biased.

Next, the surface layer 70 is applied to the ribs 62, 64 and joints 66 of the covering tip 60. Either an appropriate supporting substrate or a base film layer is positioned where the surface layer 70 is desired. The stent 10 is then coated with parylene or other film/layer materials according to known techniques.

The stent 10 is then cooled to below a transition temperature so that the stent 10 can be collapsed without plastic deformation or other permanently damaging deformation of the stent 10. The covering tip 60 is bent about the bend line 65 so that it extends substantially axially while the stent 10 is below its transition temperature. The stent 10 is installed within a delivery tube 2 which has an interior with a diameter similar to a collapsed diameter of the stent 10. The delivery tube 2 is preferably sufficient flexible to allow it to be passed through arterial pathways within the body and yet sufficiently rigid in the radial direction to resist radial expansion of the stent 10, even if the temperature of the stent 10 exceeds its transition temperature during the implantation procedure. The stent 10 and delivery tube 2 are then passed through appropriate arterial pathways until the delivery tube 2 and stent 10 are positioned where desired.

Specifically, the delivery tube 2 would be oriented directly adjacent the neck N of the aneurysm X. The delivery tube 2 is then retracted from the stent 10, along arrow E (Figure 1). As the stent 10 exits from the tip of the delivery tube 2, the stent 10 radially expands (along arrow R) to its expanded diameter. Because the covering tip 60 is biased to an orientation which extends in toward the central axis C, as soon as the covering tip 60 is out of the delivery tube 2 it begins to bend down toward the central axis C, along arrow B (Figure 2).

To ensure that the covering tip 60 is placed directly adjacent the neck N of the aneurysm X, the stent 10 and delivery tube 2 would preferably be moved slightly toward the aneurysm X as the covering tip 60 rotates down along arrow B, so that the position of the covering tip 60 is directly adjacent the neck N of the aneurysm X when the covering tip 60 has been completely rotated, to preferably substantially perpendicular to the centerline C.

The delivery tube 2 can then be further retracted, along arrow E (Figure 1) so that the extension 50 and remaining portions of the stent 10 are released from the delivery tube 2. The stent 10 is configured with a bias toward its final expanded configuration. Hence, the stent 10 expands radially, along arrow R (Figure 1) with the segments 20 forming the stent 10 engaging the walls W of the lumen L (Figure 3) so that the stent 10 is securely held in place. The stent 10 engages the wall W of the blood vessel or other lumen L with sufficient force to ensure that the stent 10 remains precisely in the desired position with the covering tip 60 overlying the neck N of the aneurysm X. Blood flow D attempting to enter the aneurysm X is thus deflected by the covering tip 60 and remains within the body lumen L. The gap 40 allows the blood flow D to continue along side branches of the body lumen L with minimal obstruction by the stent 10.

If necessary for proper positioning of the stent 10 and future monitoring, the stent 10 can be configured with radiopaque markers, either at a distal end 12 and proximal end 14 of the stent 10 or adjacent edges of the covering tip 60, or both. Such radiopaque markers can take any known prior art form, including radiopaque marker techniques disclosed in United States Patent No. 5,741,327 and United States Patent Application No. 09/192,803, for which the issue fee was paid on April 11, 2000, incorporated herein by reference.

Specifically, materials having greater radiopacity can be attached to appropriate segments 20, junctions 30, ribs 62, 64 or joints 66 or certain ones of the segments 20, junctions 30, ribs 62, 64 and/or joints 66 can merely be provided with a greater thickness to enhance their radiopacity.

With particular reference to Figures 6 and 8, details of a first alternative embodiment 110 of the stent 10 of the preferred embodiment are described. The alternative stent 110 is similar to the stent 10 of the preferred embodiment except that a unique first alternative extension 150 is provided and a unique first alternative covering tip 160 is provided. Note that the stents 10, 110 can exhibit a variety of different lengths to suit the particular needs of the implantation site. The stent 110 extends between a distal end 112 and a proximal end 114. The first alternative extension 150 couples the first alternative covering tip 160 to remaining portions of the stent 110 at the distal end 112. The first alternative extension 150 spans the gap 140 as discussed in detail with respect to the

preferred embodiment above. However, the first alternative extension 150 does not include the axial segments 52 (Figure 1). Rather, the first alternative extension 150 merely includes the series of segments 20 continuing in the same pattern throughout the stent 110 except that some segments 20 are removed to provide the alternative gap 140.

Additionally, the first alternative covering tip 160 provides an alternative to the covering tip 60 of the preferred embodiment. While the same surface layer 70 is provided in both the first alternative covering tip 160 and the covering tip 60 of the preferred embodiment, structural support within the first alternative covering tip 160 is unique. Specifically, angled ribs 162 are utilized within an interior of the covering tip 160 without any axial ribs. Perimeter ribs 164 define lateral sides of the covering tip 160. The perimeter ribs 164 extend toward each other until they are joined together at a point 169 defining an extremity of the distal end 112 of the stent 110. A bend line 165 defines a transition between the covering tip 160 and the extension 150. The covering tip 160 is essentially triangular and includes the angled ribs 162 which change in angular orientation as the stent 110 is radially expanded. The alternative covering tip 160 bends about the bend line 165 in a manner similar to that discussed above with respect to the preferred embodiment.

With particular reference to Figure 7, details of a second alternative embodiment 210 of the stent 10 of the preferred embodiment are described. The second alternative stent 210 is similar to the first alternative stent 110, except that the second alternative stent 210 includes a unique second alternative extension 250. Specifically, the second alternative extension 250 narrows down to just a single junction to minimize obstruction of blood flow through an alternative gap 240 adjacent the second alternative extension 250. While the covering tip 160 of the second alternative stent 210 is similar to the covering tip 160 shown in the stent 110 of Figure 6, the second alternative stent 210 could alternatively have a covering tip such as the covering tip 60 of the preferred embodiment or any other variation in accordance with this disclosure.

With particular reference to Figure 9, details of a third alternative embodiment 310 of the stent 10 of the preferred embodiment are described. The third alternative stent 310 provides a unique second alternative covering tip 360. The second alternative covering tip 360 uniquely provides a central rib 362 which extends axially and includes branch ribs 364 which extend in a manner skewed relative to the axial direction. A bend line 365 is provided spaced away from junctions to illustrate how midpoints in ribs can define the bend line 365. Also, seven separate ribs are crossed by the bend line to maximize the amount of structural material at the bend line 365 and enhance a strength and bending effectiveness of the stent 310. The third alternative stent 310 of the Figure 9 illustrates further how various different rib and segment configurations can be utilized to provide a stent with a covering tip according to this invention.

With particular reference to Figures 11-13, details of a fourth alternative embodiment 410 of the stent 10 of the preferred embodiment are described. In this fourth alternative embodiment, a stent 410 is provided which has a convex curving covering tip 460. Other portions of the stent 410 are similar to those described in detail above with regard to the stent 10 of the preferred embodiment.

The extension 450 spans the gap 40 (Figure 11) and the extension 450 has a configuration similar to the stent 10 of the preferred embodiment. However, some segments between the extension 450 and the covering tip 460 are shortened segments 420 (Figure 12). Specifically, the shortened segments 420 are on lateral sides of the stent 410. Regular segments 20 extend between the extension 50 and a central portion of the curving covering tip 460. Because the side shortened segments 420 are shorter than the regular segments 20 a curving bend line 465 is provided which defines a transition between the extension 450 and the curving covering tip 460. When the stent 410 is released from the delivery tube 2 and radially expands, the curving covering tip 460 will not only bend down (such as along arrow B of Figure 2), but will also curve in a convex fashion when viewed from beyond the distal end of the stent 410 (Figure 11).

The curving covering tip 460 includes axial ribs 462 and angled ribs 464 configured similarly to the axial ribs 62 and angled ribs 64 of the stent 10 of the preferred embodiment. However, axial ribs 462 adjacent sides of the curving covering tip 460 are preferably shorter in the stent 410 of the fourth alternative embodiment than in the stent 10 of the preferred embodiment.

A curving surface layer 470 spans space between the ribs 462, 464 in a manner analogous to that described above with respect to the surface layer 70 of the stent 10 of the preferred embodiment. A free edge 472 of the curving surface layer 470 defines a lowermost extent of the covering tip 60. Figure 13 illustrates the stent 410 of the fourth alternative embodiment after being fully deployed and with the curving covering tip 460 extending beyond the centerline C passing through the stent 410 within the wall W of the lumen L.

While the stent 410 of the fourth alternative embodiment reveals a preferred configuration should a curving covering tip 460 be desired, various differing curving covering tips could alternatively be provided. For instance, the curving covering tip could be concave with lengthened side segments replacing the shortened side segments 420 of the stent 410.

This disclosure is provided to reveal a preferred embodiment of the invention and a best mode for practicing the invention. Having thus described the invention in this way, it should be apparent that various different modifications can be made to the preferred embodiment without departing from the scope and spirit of this disclosure. When structures are identified as a means to perform a function, the identification is intended to include all structures which can perform the function specified.

Industrial Applicability

This invention exhibits industrial applicability in that it provides a radially expandable stent which includes a covering surface which can be flexibly deployed when the stent is radially expanded to block a neck of an aneurysm, such as a brain aneurysm within a blood vessel.

Another object of the present invention is to provide a stent which can radially collapsed sufficiently to pass through small arterial pathways within a delivery tube, such as arterial pathways leading to brain aneurysm sites, and be radially expanded to a diameter sufficiently large to securely hold position within the blood vessel adjacent the aneurysm.

Another object of the present invention is to provide a stent for treatment of aneurysms which can be implanted without direct surgery and which can be securely held in position adjacent the aneurysm without imparting any damaging stresses upon the aneurysm itself which might cause rupture of the aneurysm.

Another object of the present invention is to provide a stent which can block an aneurysm in a blood vessel with a branching side pathway nearby and not block blood flow in the side pathway.

Another object of the present invention is to provide a stent which includes a covering tip which extends at least partially in towards the center line of the stent when the stent is radially expanded, such that a central pathway through the stent is at least partially blocked by the covering tip.

Another object of the present invention is to provide a radially expandable stent which can be implanted within a body lumen, such as a blood vessel, which is faced by a neck of an aneurysm and with various branches of the lumen on either side of the aneurysm with the stent covering the neck of the aneurysm and leaving the lumen branches substantially unobstructed adjacent the aneurysm.

Another object of the present invention is to provide a stent which includes a covering tip which can be initially oriented substantially axially and which bends in toward a central axis of the stent when the stent is radially expanded.

Other further objects of the present invention will become apparent from a careful reading of the included drawing figures, the claims and detailed description of the invention.

CLAIMS

What is claimed is:

Claim 1 - A radially expandable stent comprising in combination:

a plurality of segments joined together to exhibit a substantially cylindrical contour for said stent between a distal end and a proximal end; and

at least one rib extending out of said cylindrical contour and at least partially toward a central axis of said stent.

Claim 2 - The stent of Claim 1 wherein said rib extends radially a distance greater than a radius of said stent.

Claim 3 - The stent of Claim 2 wherein a surface is coupled to said rib.

Claim 4 - The stent of Claim 3 wherein said stent includes at least two ribs spaced from each other, said surface extending between said at least two ribs.

Claim 5 - The stent of Claim 4 wherein said surface is oriented non-parallel to said central axis of said stent.

Claim 6 - The stent of Claim 5 wherein said surface is located adjacent said distal end of said stent.

Claim 7 - The stent of Claim 6 wherein a gap is provided between said surface and portions of said stent between said distal end and said proximal end, said gap larger than space between said plurality of segments; and

wherein at least one segment extends across said gap between said at least one rib and portions of said stent adjacent said gap.

Claim 8 - The stent of Claim 1 wherein said stent includes a flexible surface coupled to said at least one rib, said surface more flexible than said rib.

Claim 9 - The stent of Claim 8 wherein said surface is oriented non-parallel to said central axis of said stent; and

wherein said surface is located adjacent said distal end of said stent.

Claim 10 - The stent of Claim 9 wherein said surface at least partially blocks an interior of said stent.

Claim 11 - The stent of Claim 10 wherein said segments of said stent and said at least one rib of said stent are formed from a material which has a bias toward a final position with said surface and said rib oriented non-parallel to said central axis and said material exhibiting sufficient flexibility to allow said ribs to be orientable in an original position with said surface and said stent collapsed substantially axially parallel to said central axis, said stent including a bend line defining a point on said at least one rib where said stent bends when transitioning between said original position and said final position.

Claim 12 - A radially expandable stent having a tip for covering an aneurysm, the stent comprising in combination:

at least one segment defining a substantially cylindrical contour of said stent surrounding a center line of said stent;

said stent including a proximal end and a distal end; and

said distal end including a surface extending at least partially in toward said center line.

Claim 13 - The stent of Claim 12 wherein said surface includes at least one rib, said surface more flexible than said rib.

Claim 14 - The stent of Claim 13 wherein said at least one rib is attached to said at least one segment, said at least one rib and said at least one segment both formed from a common material having a bias toward a final configuration with said at least one rib extending at least partially radially away from said at least one segment and at least partially toward said center line.

Claim 15 - The stent of Claim 14 wherein said at least one rib and said at least one segment are formed from a metallic alloy including nickel and titanium therein.

Claim 16 - The stent of Claim 15 wherein said surface is formed from at least one polymer in the family of polymeric di-para-zylenes.

Claim 17 - The stent of Claim 12 wherein said surface is spaced from at least a portion of said stent by a gap adjacent said surface, said gap defining a region of said stent left unfilled by said at least one segment, such that blood flow out of said cylindrical contour of said stent can occur without impedance by said at least one segment.

Claim 18 - A surface for covering a neck of an aneurysm, comprising in combination:

at least one rib;

a flexible film attached to said rib, said film at least as wide as a thinnest width portion of the neck of the aneurysm, such that said film can at least partially block the aneurysm when located adjacent the neck;

an elongate stent structure; and

said at least one rib coupled to said elongate stent structure and oriented non-parallel with a long axis of said stent structure.

Claim 19 - The apparatus of Claim 18 wherein said stent structure is substantially cylindrical and includes at least one segment capable of flexing to radially expand said cylindrical contour of said stent structure.

Claim 20 - The apparatus of Claim 19 wherein said stent structure includes a gap between said flexible film and said stent structure, said gap spanned by fewer segments of said stent than portions of said stent structure spaced from said gap.

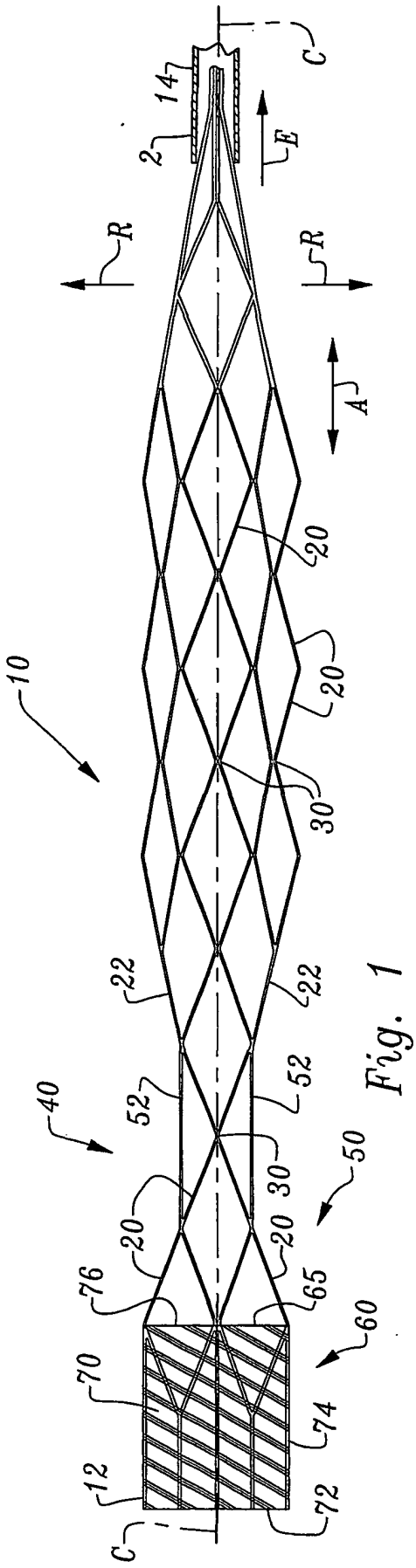
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Fig. 1

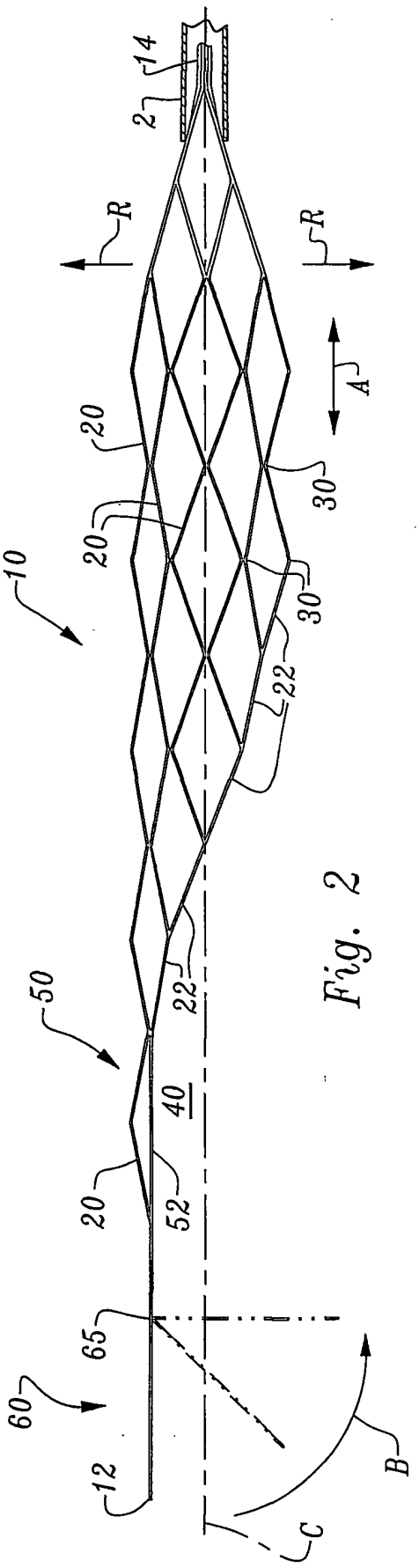
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Fig. 2

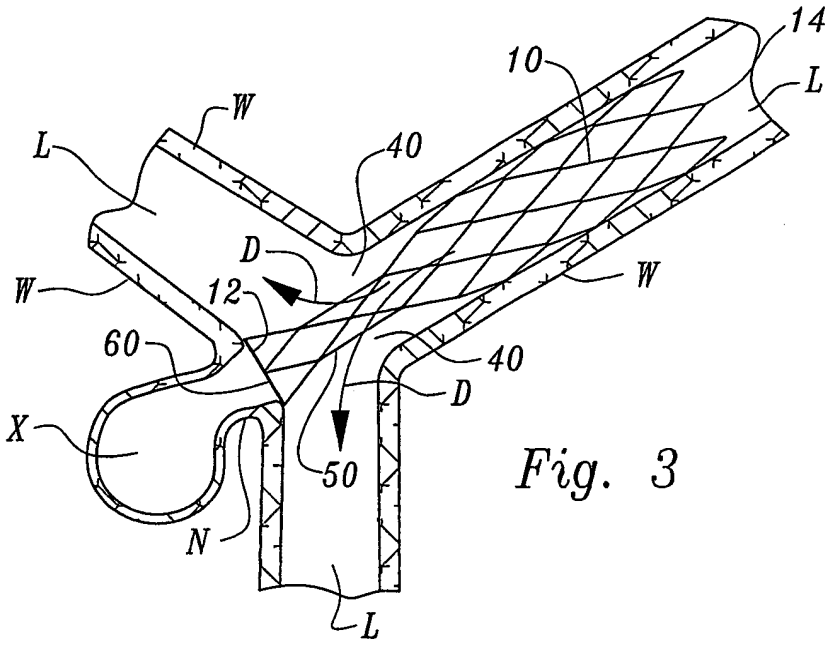


Fig. 3

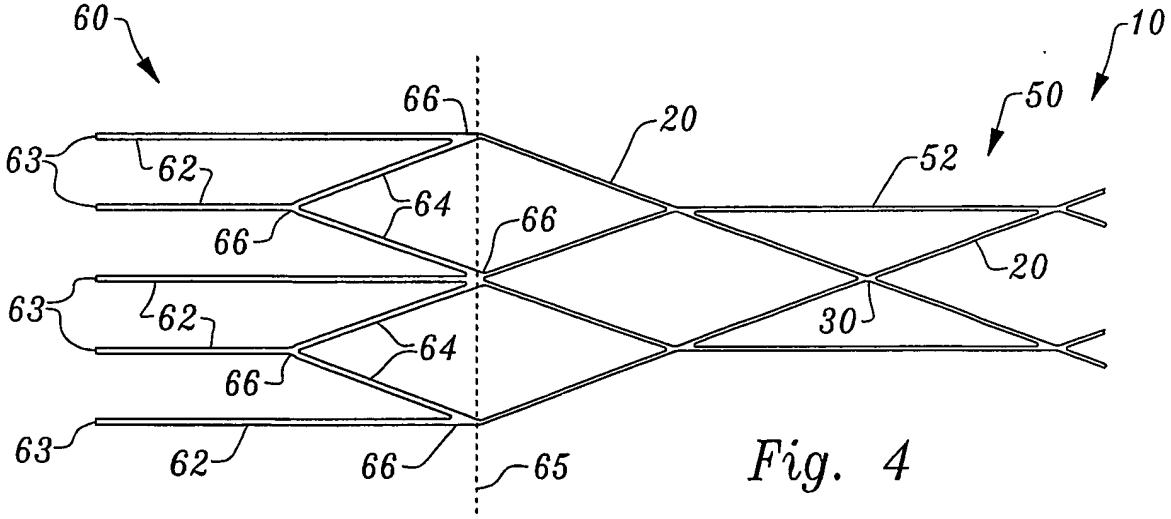
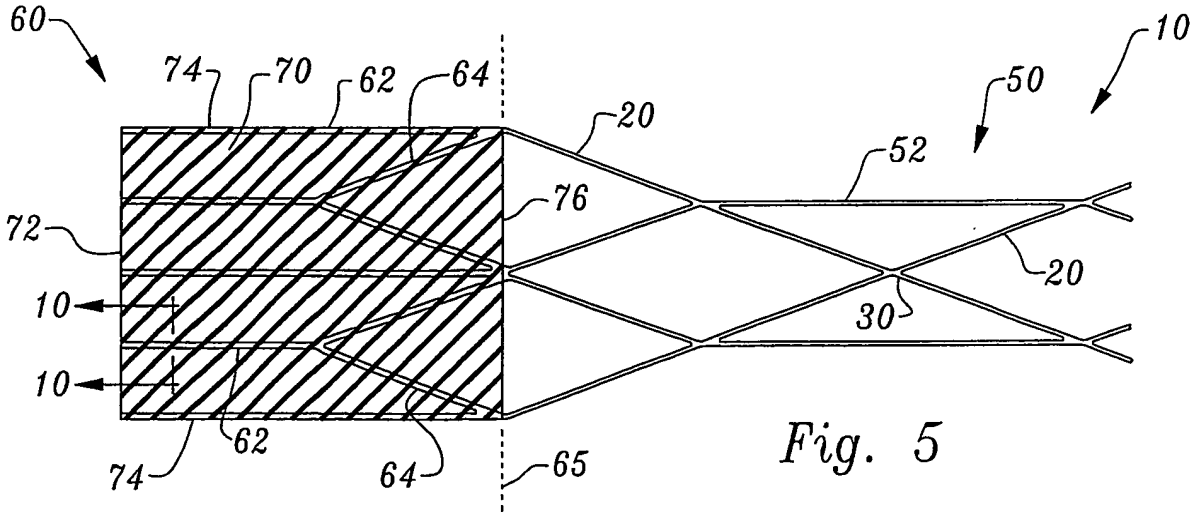


Fig. 4



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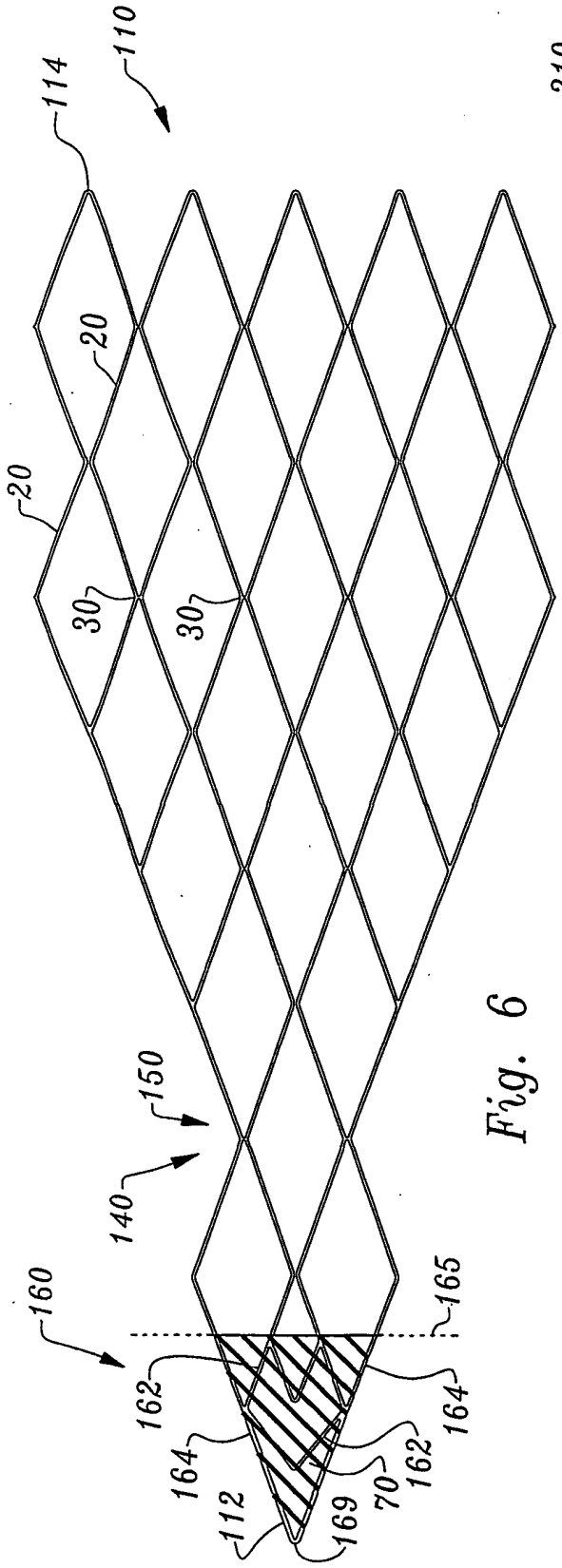
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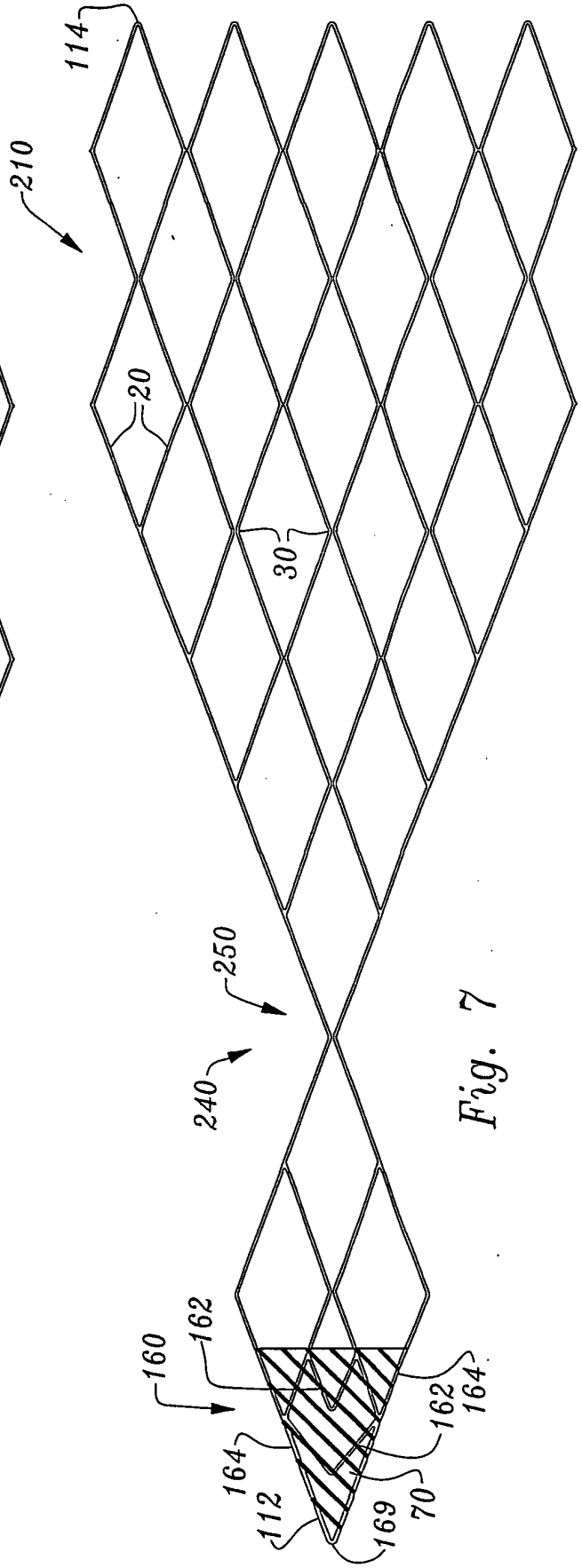
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Fig. 7

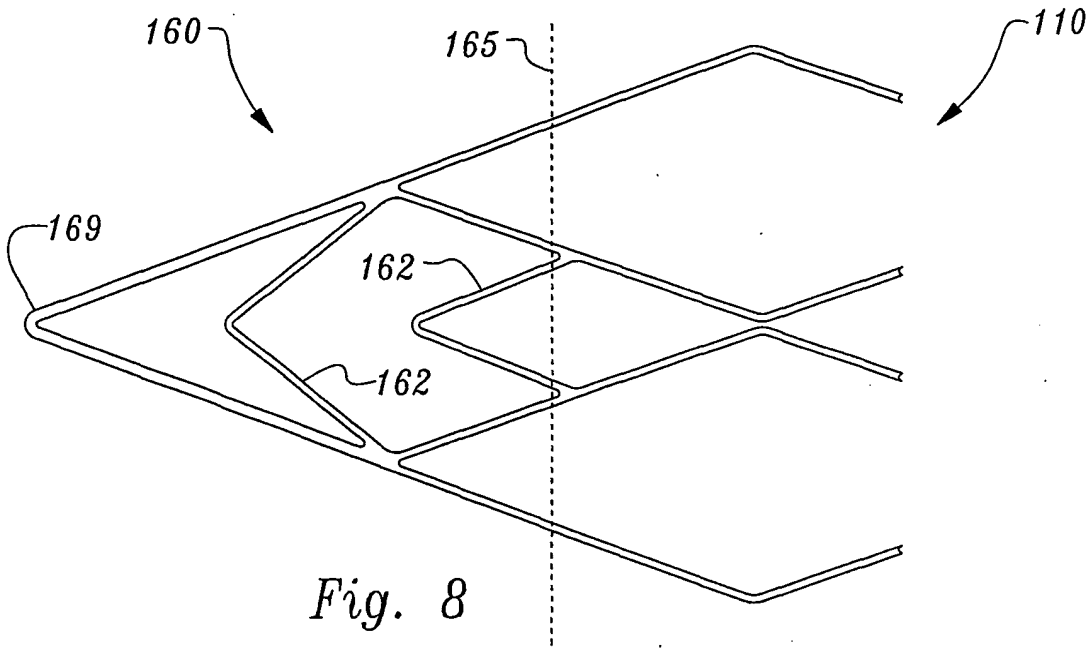

Fig. 8

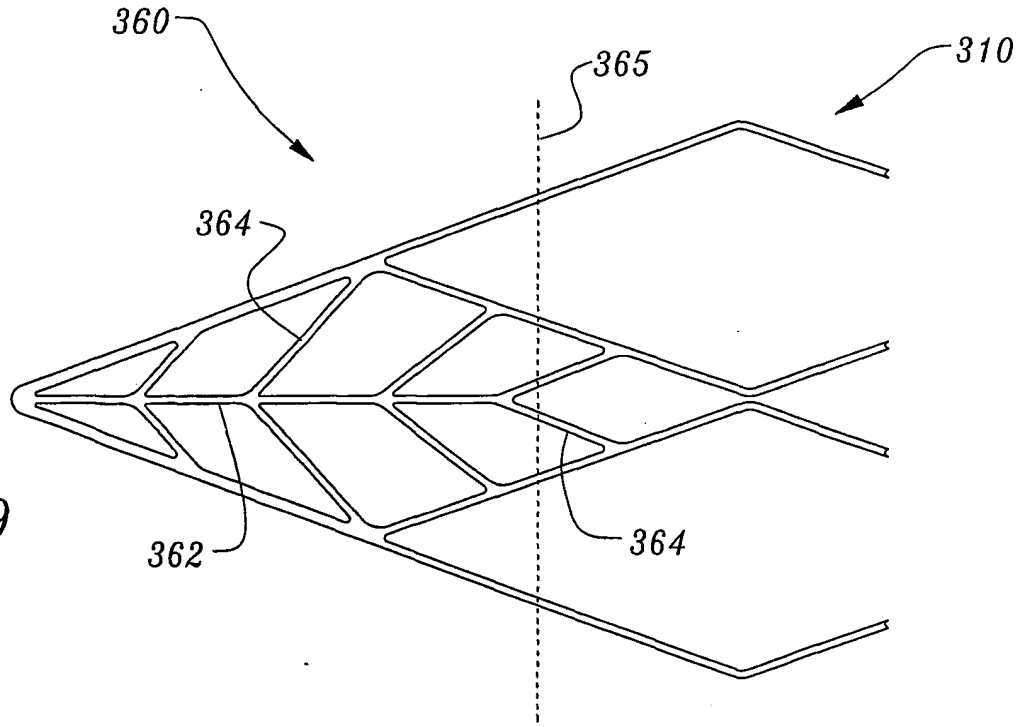

Fig. 9

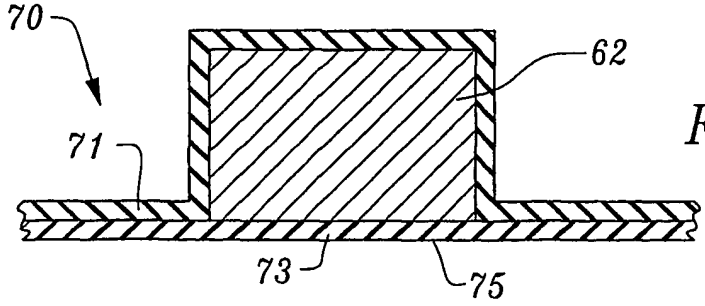

Fig. 10

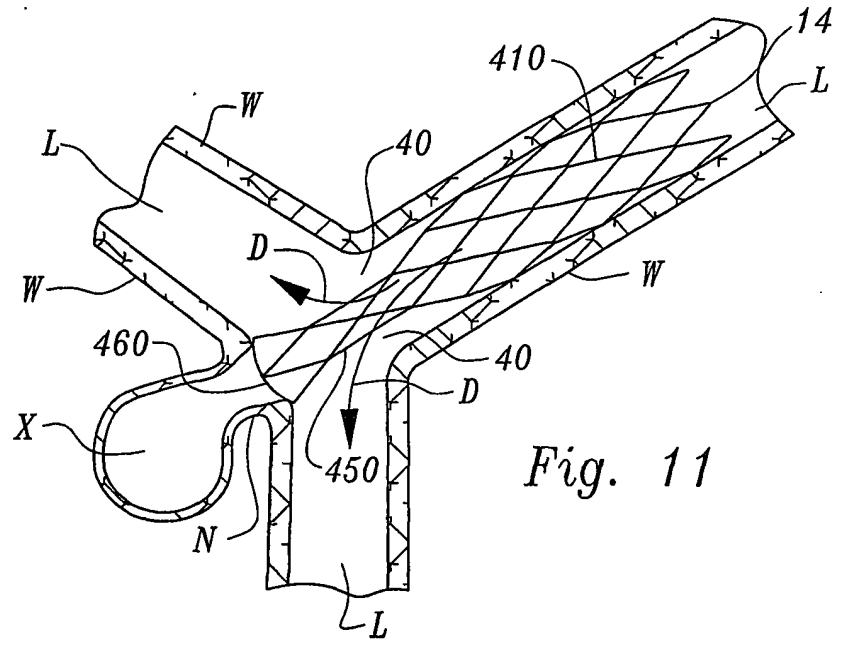

Fig. 11

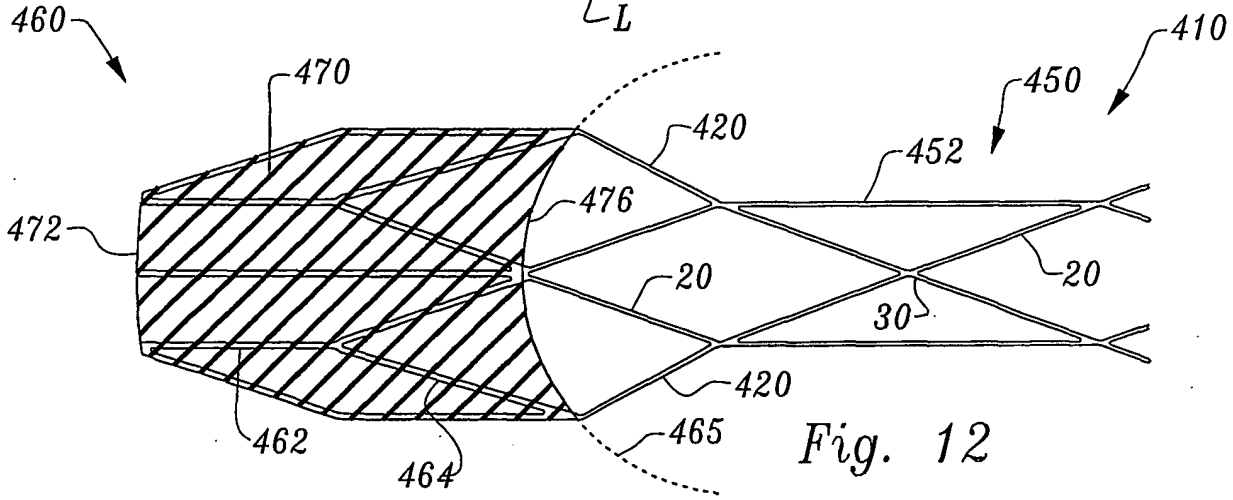

Fig. 12

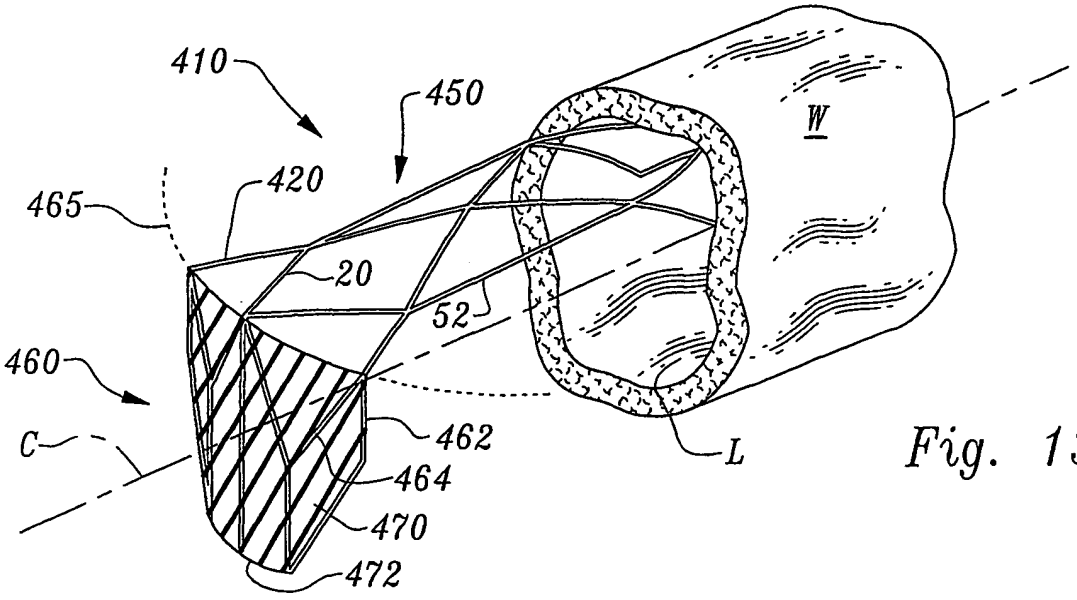

Fig. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/18507

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/06; A61M 29/00
US CL : 623/1.1-1.31; 606/200
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1.1-1.31; 606/200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST: stent, aneurysm, trap, impermeable membrane

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,919,224 A (THOMPSON et al) 06 JULY 1999, see Fig. 13 and Fig. 3.	1-3, 8-10, 12--15, 18-19

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 21 AUGUST 2001	Date of mailing of the international search report 18 OCT 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer VY Q. BUI Diane Smith Telephone No. (703) 306-3420